IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT AND INTERFERENCES

Appl. No.	:	09/918,445	Confirmation No. 4697
Applicant	:	Ricci et al	
Filed	:	December 19, 2001	
TC/A.U.	:	1714	
Examiner	:	Tae H. Yoon	
Docket No.	:	1065.26(B)	
Customer No.:		27353	

For: Implant Composition With Controlled Resorption Rate for Stimulating Bone Growth and Method of Use

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandra, VA 22313-1450

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Sir:

The Commissioner is hereby authorized to charge Appeal Brief Fee under 37 CFR1.17(b) in amount of $165.00 to Deposit Account 502,557 and any additional fees required or to credit for any excess fee paid.

10/14/03
Date of Signature

By: _____
Melvin K. Silverman
Registration No. 26,234
Telephone: (954) 351-7474

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1. REAL PARTY IN INTEREST

Real party in interest in this appeal is the inventors John Ricci, Harold Alexander, Harriett Naiman (as executrix of Charles Naiman) and Bruce L. Hollander.

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There are no appeals or interferences known to Appellants, or the Appellant's legal representatives which will directly affect or be directly affected by or have a bearing on the Board's Decision in the pending appeal.

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The present application originally contained Claims 1-13. Claims 1-4, 8 and 10-11 were cancelled, and Claims 14-19 were added by Amendment dated October 3, 2002. Claim 6 was cancelled by Amendment After Final dated May 27, 2003. Currently, Claims 5, 7, 9 and 12-19 are pending. All claims are implant claims, and only Claim 14 is presented in independent form. No claim has been allowed.

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5. SUMMARY OF THE INVENTION

The invention underlying this appeal addresses the technical problems of providing an orthopedic implant system comprising implant element for surgical insertion into a bone, replacing a joint of a patient, the surface of the implant having an ordered microgeometric repetitive surface pattern in the form of a multiplicity of alternating ridges and grooves, each having an established width in a range of about 2.0 to about 25 microns (micrometers) and an established depth in a range of about 2 to about 25 microns, in which said microgeometric repetitive surface patterns define a guide for promotion of the rate, orientation and direction of growth of colonies of cells of said bone which is in contact with said surface pattern.

6. ISSUE

(1) Appended Claims 5, 9, 14, 18 and 19 which are on Appeal have been rejected under 35 USC §102(b), as being anticipated by Branemark et al (US 4,330,891).

Claim 14 is an independent claim and Claims 5, 9 and 18-19 are dependent claims of Claim 14. Claim 14 was equivalent to the cancelled Claim 1, except for modifications to overcome §112 rejection. In the Response to the first Office

Action dated October 3, 2002, Appellants pointed out to the Examiner that Branemark et al.'s "micro-pitted" surface is in a range of 10-1,000 nanometers which is outside the range of Appellants' claimed dimension of alternating ridges and grooves. Appellants further pointed out to the Examiner that Branemark et al.'s pits differ from Appellants' claimed repetitive surface pattern.

The Examiner maintained the rejection of Claims 5, 9, 14 and 18-19 under 35 USC §102(b) based on the same prior art in the final Office Action dated January 2, 2003. The Examiner argued that given that a micron is such a small unit of length, 1.0 micron will fall in range of "of about 2 microns" as claimed in Claim 14. The Examiner further argued that the dictionary definition of "repetitive" defines it as containing repetition and such a definition applies to Branemark et al.'s "micro-pitted surface".

The following issue is therefore presented for review by the Board of Patent Appeals and Interferences:

> Is it appropriate for the Examiner to reject Appellants' implant claims comprising a micro-geometric, repetitive surface pattern in a form of a multiplicity of substantially parallel alternating ridges and grooves, each having an established width of about 2 to about 25 microns and depth of about 2 to about 25 microns under 35 USC §102(b), by arguing that Branemark et al's micro-pit of 10-1,000 nanometers (equivalent to 0.01-1 micron), overlaps with 2 microns, and by arguing that randomly distributed micro-pits are equivalent to Appellant's claimed specifically defined repetitive surface pattern according to the dictionary definition of the term of repetitive?

(2) Appended Claims 5, 7, 9 and 12-19 which are on Appeal have been rejected under 35 USC §102(e), as being anticipated by Naiman et al (US 5,607,607).

The Examiner rejected Claims 1-13 under 35 USC §102(e) as being anticipated by Naiman et al (US 5,607,607) in the first Office Action dated April 5, 2002. Appellants submitted a copy of Declaration under 37 CFR 1.131 which was previously submitted in the prosecution of the parent application Serial No. 09/500,038 (now U.S. Patent No. 6,419,491). Appellants further pointed out in the Response dated October 3, 2002 that the Declaration sets forth that the instant invention predated the effective date of Naiman et al (5,607,607) of November 1, 1993. However, the Examiner maintained the same rejection of pending Claims 5, 7, 9 and 12-19 in the final Office Action, without providing a reason why the Declaration was not considered and what was further required from the Appellant in order to overcome this rejection.

Therefore, the second issue is presented for review by the Board of Patent Appeals and Interferences:

Is it appropriate for the Examiner to reject the implant claims when Appellants have clearly demonstrated that the conception and reduction to practice of the instant invention are prior to the effective date of the prior art?

(3) Appended Claims 5, 7, 9, 14-16 and 19 which are on Appeal have been rejected under 35 USC §103(a), as being unpatentable over Lin et al. (US 4,778,469) in view of Mears (US 4,553,272).

Appellants presented to the Examiner in the Response to the first Office Action dated October 3, 2002 that Lin's teaching of a dissolvable spacer used in a calcium sulfate acid etch process on a plastic surface is not applicable to

Appellants' claimed invention. Appellants further presented to the Examiner that Mears merely teaches pores that have no particular arrangement or pattern. The Examiner maintained the rejection in the final Office Action by arguing that the dictionary definition of the term "repetitive" applies to Mears' porous surface and that Mears' pore size range of 25 microns reads on the claimed about 2 to about 25 microns.

Therefore, the third issue is presented for review by the Board of Patent Appeals and Interferences:

Is it appropriate for the Examiner to reject the implant claims by merely arguing that Mears' pore size range of 25 microns overlaps with Appellant's claimed range of about 2 to about 25 microns and that Mears' pores are "repetitive" according to the dictionary, while completely neglecting Appellants' description and definition of the term "repetitive surface pattern" in a form of a multiplicity of substantially parallel alternating ridges and grooves which have an established width of about 2 to about 25 microns and depth of about 2 to about 25 microns?

7. GROUPING OF CLAIMS

For the purpose of this appeal only, Appealed Claims 5, 7, 9 and 12-19 may be grouped together and it may be presumed that in regard to patentability that the Appealed claims stand or fall together.

8. ARGUMENT

(A) Claims 5, 9, 14, 18, and 19 have been rejected under 35 U.S.C. 102(b) as anticipated by Branemark, et al (U.S.P.N. 4,330,891), this on the basis that Branemark discloses an element with a micro-pitted surface for the growing of tissue of a particular type. While Branemark relates that his pit size has an upper

limit which corresponds to that of certain cell diameters, the process of micro-pitting to form a "micro-pitted surface" that is taught by Branemark relates to a surface pattern which is inherently random in character.

Further, even if Branemark did have in mind a particular surface pattern for his micro-pitted surfaces, that pattern is not suggested in any manner in his specification which does not contain any drawings. That is, notwithstanding the language of the Abstract (Lines 19-21 thereof) that the micro-pitted surfaces of Branemark may include elements that "may be shaped with grooves, corrugations, channels, etc, and be provided with an opening for tissue to grow through" still does not provide any specific suggestion of order, directionality or the like, much less a repetitive surface pattern as is taught by Appellants.

More importantly, while not teaching any type of repetitive surface pattern, given that 1000 nanometers equal 1 micron, the uppermost range of the magnitude of the micro-pits (or other structure) suggested by Branemark is but one-half of the low end (two microns) of the Appellants range (2-25 microns) of repetitive parallel alternating ridges and grooves. As such, most of the range of 10-1000 nanometers of Branemark constitutes a surface far too smooth to produce an orientation and directionality of growth of colonies of cells having sufficient contact with an implant surface. Further, Branemark notes (Col. 2, Line 41 thereof, that his preferred range is 10 to 30 nanometers (0.03 microns) thereby falling well below the low end of Appellants' range of dimensions. It is, thereby, to be appreciated that not only is the order of magnitudes of the "pits" of Branemark below that of Appellants' claimed range but, in addition, there is no teaching of the use of a repetitive surface pattern of any type, notwithstanding Branemark's comments that his elements may be shaped with grooves, corrugations, channels and the like. In fact, it is unclear from such language whether Branemark simply intends that his micro-pitted surface can be applied to an implant having grooves, corrugations and channels or, alternatively, whether or not such grooves,

corrugation and channels are the micro-pits. That is, Branemark apparently uses the term "element" to mean implant and that the implant may have both grooves and micro-pits.

With respect to the Examiner's assertion that "a micron is such a small unit of length, 1.0 micron (1000 nanometers)" it falls within the range of "about 2 microns," Appellants respectfully disagree. It is important to point out that regardless how small a unit is, the unit defines a definitive measurement range. Within that range, one "small" number can be significantly different from another "small" number. Therefore, it is only appropriate to judge whether two numbers overlap within the scope of a specifically defined unit, not how small that unit is.

More particularly, the Federal Circuit has held that the ordinary and accustomed meaning of "about" is "approximately." See Canopco., Inc. v. May Dept Store Co., 46 F.3d 1556, 1561 n.2 (Fed. Cir. 1994), quoting Webster's Third New International Dictionary. Further, Blacks Law Dictionary (7th Ed. 1999) defines "about" as approximately. In Modine Mfg. Co. v. U.S. International Trade Commission, 75 F. 3d 1545, 1554 (Fed. Cir. 1996), the Federal Circuit stated that the term "about" must be viewed by the decision maker as they would be understood by persons experienced in the field of the invention. Although it is rarely feasible to attach a precise limit to "about," the usage can usually be understood in light of the technology embodied in the invention."

Appellants particularly refer to Frilette v. Kimberlin, 412 F.2d. 1390, 1399 (CCPA 1969). In this interference case, prior art reciting a range of 3 to 5 Angstroms pore diameters of cyrstals was held not to read upon Applicant's range of pore diameters of about 6 to 15 Angstroms. [Emphasis added.] With the issue at hand, Branemark teaches micro-pits in a range of 10-1000 nanometers. This upper end of 1000 nanometers is substantially different from Appellants' lower end of about 2000 nanometers, therefore, it does not overlap with Appellants' claimed

range of dimension.

With further regard to the Abstract of Branemark, it is noted, at Line 9 thereof that "Optimal result are obtained with pore diameters equal to or smaller than 300 nanometers..." which is consistent with Branemark's recitation of the 10 to 300 nm range in Col. 2, Line 41 of his specification. Therein, it is also clear that Branemark equates a pore to a micro-pit. It is also clear that the pore size of Branemark is at its high end, one-half of the low end of the range of Appellants and, at its low end, .005 of the low end of Appellants' range. This fact taken in combination with the complete absence of any enabling teaching as to whether or not Branemark contemplated any form or repetitive surface pattern in that range, whether with or without grooves, corrugations, or channels, renders Branemark inoperative as a teaching or anticipatory reference.

With regard to the Examiner's argument related to the term "repetitive", Appellants urge that a dictionary definition of the term "repetitive" is not appropriate given that the Appellants have presented a lengthy specification, including many illustrations, to define their use of the term "repetitive" in the context of their invention (See for example Fig. 7 thru 14A of the Drawings and the description thereof at Pages 20-23 of the specification).

Therefore, Appellants maintain that Appellants' claimed invention is not anticipated or implied by Branemark et al.

(B) Claims 5-7, 9 and 12-19 have been rejected under 35 U.S.C. 102(e) as anticipated by Naiman, et al (U.S.P.N. 5,607,607). Appellants however have submitted a copy of the declaration of co-inventor John L. Ricci (see Declaration of November 23, 2001) in regard to Application Serial No. 09/500,038, which was furnished as an enclosure to Appellants' response of October 8, 2002. This declaration indicates that the present invention was conceived and reduced to

practice prior to the effective date (November 1, 1993) of Naiman et al. See 5 and 6 of said Declaration. As such, Naiman '607 cannot stand as a reference with respect to Claims 5-7, 9 and 12-19.

(C) Claims 5-7, 9, 14-16 and 19 were rejected under 35 U.S.C. 103(a) as unpatentable over Lin (U.S.P.N. 4,778,769) in view of Mears (U.S.P.N. 4,553,272) in the final Office Action. Therein, the Examiner appears to rely upon Mears' teaching of the use of "open pores of an average size of about 25 to 75 microns and a second series of open pores of average size of about 100 to 400 microns..." (See last sentence of Abstract of Mears). However, Appellants, as above noted, do not employ pores but, rather, employ a specific repetitive surface pattern in the form of multiplicity of substantially parallel ridges and grooves, each having an established width in a range of about 2 to about 25 microns and an established depth within a like range of dimensions. Accordingly, neither the geometry nor the dimensionality of Mears is congruent with that of the Appellants. Further, the teaching of Mears does not relate to an orthopedic implant but, rather, to one which addresses issues of soft tissue, namely, cartilages, tendons, ligaments, and musculo-tendenous cells which, while relative to certain areas of joint reconstruction, do not relate an implant for the surgical insertion into a bone or bone-related tissue of a patient.

From the illustration of Fig. 1 of Mears, it is clear that the use thereof is contemplated to re-establish a ball-and-socket hip joint of a patient. This may be fairly compared to Fig. 20 of Appellants' specification in which, as may be noted, the Appellants' micro-geometric repetitive surface pattern is applied to the stem 106 and shoulder 110 of a hip implant but not to ball portion 130 thereof which is the area to which Mears would have application.

Further, from the enlarged radial cross-sectional view of Fig. 2 of Mears, the lack of order to the pores 12 of Mears is also apparent, as is that of pores 44

and 46 of Figs. 3 and 5 in which Mears shows a dental application of his soft tissue implant. It is further noted that the only actual teaching of Mears is that his pores occupy between about 20 and about 50 percent of the total volume of the portion of the implant upon which they are used. (See Col. 3, Line 59 to 63). Accordingly, there is no order or pattern in the use of the open pore geometry of Mears other than that their total volume occupy 20 to 50 percent of the volume of the implant surface to which they are applied.

With regard to the reference to Lin, which the Examiner has applied as a teaching reference in combination with Mears, it is respectfully noted that Lin relates to a dissolvable spacer used in a calcium sulfate acid etch process upon a plastic surface. Thereby, the acid etch mask and process of Lin is not applicable to high density materials such as titanium, stainless steel, ceramics, Hench glass and combinations thereof employed as a base material in Appellants' implant. The present application makes reference to such high density base material of the implant in Claims 5 and 18 of the application. As noted by Appellants at Page 7, the first paragraph, of the specification, Lin employs an acid soluble spacer which contains a pattern to be transferred to the implant surface which, as such, is positioned upon a desired portion of the implant surface to be texturized. The spacer is then pressed into the implant surface and is then removed by treating it with an acid. This process, as above noted, is not applicable to the high density materials which must be employed in any orthopedic application of Appellants' invention.

In addition to the above, Lin and Mears, however combined, do not teach an essential limitation of Appellants invention, namely, a repetitive surface pattern in the form of multiplicity of substantially parallel alternating ridges and grooves. That is, as may be seen in Figs. 1-3 of Lin, the geometry thereof is not one of substantially parallel ridges and grooves but, rather, is one more akin to a honeycomb pattern. This pattern is described by Lin at Col. 2, Lines 53-56 to the

effect that "pattern 14 includes tapered post 16 with undercuts 18 as well as pyramids 17 and triangular ridges 19, as shown in Figs. 3 and 5." The process by which this rather complex geometry is formed is further described by Lin at Col. 3, Lines 17-19 thereof. As such, Mears does not teach the use of substantially parallel pattern of alternating ridges and grooves. And certainly, does not suggest any dimensionality whatsoever. Thereby, Lin and Mears, however combined, do not teach a high density implant element having the limitations of dimension and geometry claimed by Appellants. In fact, these limitations are critical in the accomplishment of the objects of the invention, as is set forth in Appellants' Declaration under 37 C.F.R. 1.132 (combined with said 1.131 Declaration) furnished as Enclosure 4 with Appellants' Amendment/Response of October 8, 2002. Therein, the remarks made relative to Wagner (U.S.P.N. 5,989,027) in ¶10-13 of said Declaration which relate to an essentially random, irregular porous surface, are equally applicable to the random open pore structure of Mears. Therefore, the references to Lin and Mears, however combined, do not render obvious Appellants' Claims 5-7, 9, 14-16 and 19.

Furthermore, as discussed previously, with regard to the Examiner's argument related to the term "repetitive", Appellants urge that a dictionary definition of the term "repetitive" is not appropriate given that the Appellants have presented a lengthy specification, including many illustrations, to define their use of the term "repetitive" in the context of their invention (See for example Fig. 7 thru 14A of the Drawings and the description thereof at Pages 20-23 of the specification).

Therefore, Appellants maintain that Appellants' claimed invention is not obvious in view of the prior art.

9. CONCLUSION

Accordingly, for all the reasons expressed above, the final rejection of the Claims on Appeal should be reversed by the Board and the extant claims of the application should be allowed to issue.

10-14-03
Date of Signature

By: _____
Melvin K. Silverman
Reg. No. 26,234
Attorney for Appellant

Address correspondence to:

Melvin K. Silverman
500 Cypress Creek Road
Suite 500
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APPENDIX A – CLAIMS ON APPEAL

5. (Previously presented). The implant as recited in Claim 14 in which base materials of said implant are selected from the group consisting of the materials of titanium and alloys thereof, stainless steel, ceramics, biocompatible glass and combinations thereof.

7. (Previously presented). The implant as recited in Claim 14 in which said repetitive micro-geometric pattern of ridges and grooves comprises application to surfaces of said implant element in orientations which, relative to a longitudinal axis of said implant, are selected from the group consisting of vertical, horizontal, orthonormal diagonal, radial, circumferential, and concentric orientations.

9. (Previously presented). The implant as recited in Claim 14 in which said orthopedic implant is selected from the group consisting of hip, knee, shoulder, elbow, ankle and finger implants.

12. (Original). The implant as recited in claim 9 comprising different zones furnished with respectively different surface patterns.

13. (Original). The implant as recited in Claim 12 in which said different zones include respective hard and soft tissue contact zones

14. (Previously presented). An orthopedic implant comprising an implant element for surgical insertion into a bone or bone-related tissue of a patient, said implant element comprising a micro-geometric, repetitive surface pattern in a form of a multiplicity of substantially parallel alternating ridges and grooves, each having an established width in a range of about 2 to about 25 microns, and an established depth in a range of about 2 to about 25 microns,

whereby said micro-geometric repetitive pattern defines a guide for a promotion of the rate, orientation and direction of growth of colonies of cells of said bone which are in contact with said surface pattern.

15. (Previously presented). The implant as recited in Claim 14, in which said implant element comprises a grid-like matrix of said pattern of alternating ridges and grooves.

16. (Previously presented). The implant as recited in Claim 14, in which said alternating ridges and grooves are oriented in parallel with a longitudinal axis of said implant.

17. (Previously presented). The implant as recited in Claim 14, in which said alternating ridges and grooves are oriented transversely to said longitudinal axis of said implant.

18. (Previously presented). The implant as recited in Claim 5, in which the surface of said implant element comprises a surface selected from the group of surfaces consisting of hydroxyapatite, RBM roughening, titanium, plasma sprayed, calcium sulfate, biocompatible glass, collagen, growth factor compounds, and combination thereof.

19. (Previously presented). The implant as recited in claim 9, in which said repetitive micro-geometric pattern is [comprises] a product of the process group consisting of laser etching, acid etching, mechanical etching, and photolithography.

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The following issue is therefore presented for review by the Board of Patent Appeals and Interferences:

> Is it appropriate for the Examiner to reject Appellants' implant claims comprising a micro-geometric, repetitive surface pattern in a form of a multiplicity of substantially parallel alternating ridges and grooves, each having an established width of about 2 to about 25 microns and depth of about 2 to about 25 microns under 35 USC §102(b), by arguing that Branemark et al's micro-pit of 10-1,000 nanometers (equivalent to 0.01-1 micron), overlaps with 2 microns, and by arguing that randomly distributed micro-pits are equivalent to Appellant's claimed specifically defined repetitive surface pattern according to the dictionary definition of the term of repetitive?

(2) Appended Claims 5, 7, 9 and 12-19 which are on Appeal have been rejected under 35 USC §102(e), as being anticipated by Naiman et al (US 5,607,607).

The Examiner rejected Claims 1-13 under 35 USC §102(e) as being anticipated by Naiman et al (US 5,607,607) in the first Office Action dated April 5, 2002. Appellants submitted a copy of Declaration under 37 CFR 1.131 which was previously submitted in the prosecution of the parent application Serial No. 09/500,038 (now U.S. Patent No. 6,419,491). Appellants further pointed out in the Response dated October 3, 2002 that the Declaration sets forth that the instant invention predated the effective date of Naiman et al (5,607,607) of November 1, 1993. However, the Examiner maintained the same rejection of pending Claims 5, 7, 9 and 12-19 in the final Office Action, without providing a reason why the Declaration was not considered and what was further required from the Appellant in order to overcome this rejection.

Therefore, the second issue is presented for review by the Board of Patent Appeals and Interferences:

Is it appropriate for the Examiner to reject the implant claims when Appellants have clearly demonstrated that the conception and reduction to practice of the instant invention are prior to the effective date of the prior art?

(3) Appended Claims 5, 7, 9, 14-16 and 19 which are on Appeal have been rejected under 35 USC §103(a), as being unpatentable over Lin et al. (US 4,778,469) in view of Mears (US 4,553,272).

Appellants presented to the Examiner in the Response to the first Office Action dated October 3, 2002 that Lin's teaching of a dissolvable spacer used in a calcium sulfate acid etch process on a plastic surface is not applicable to

Appellants' claimed invention. Appellants further presented to the Examiner that Mears merely teaches pores that have no particular arrangement or pattern. The Examiner maintained the rejection in the final Office Action by arguing that the dictionary definition of the term "repetitive" applies to Mears' porous surface and that Mears' pore size range of 25 microns reads on the claimed about 2 to about 25 microns.

Therefore, the third issue is presented for review by the Board of Patent Appeals and Interferences:

Is it appropriate for the Examiner to reject the implant claims by merely arguing that Mears' pore size range of 25 microns overlaps with Appellant's claimed range of about 2 to about 25 microns and that Mears' pores are "repetitive" according to the dictionary, while completely neglecting Appellants' description and definition of the term "repetitive surface pattern" in a form of a multiplicity of substantially parallel alternating ridges and grooves which have an established width of about 2 to about 25 microns and depth of about 2 to about 25 microns?

7. GROUPING OF CLAIMS

For the purpose of this appeal only, Appealed Claims 5, 7, 9 and 12-19 may be grouped together and it may be presumed that in regard to patentability that the Appealed claims stand or fall together.

8. ARGUMENT

(A) Claims 5, 9, 14, 18, and 19 have been rejected under 35 U.S.C. 102(b) as anticipated by Branemark, et al (U.S.P.N. 4,330,891), this on the basis that Branemark discloses an element with a micro-pitted surface for the growing of tissue of a particular type. While Branemark relates that his pit size has an upper

limit which corresponds to that of certain cell diameters, the process of micro-pitting to form a "micro-pitted surface" that is taught by Branemark relates to a surface pattern which is inherently random in character.

Further, even if Branemark did have in mind a particular surface pattern for his micro-pitted surfaces, that pattern is not suggested in any manner in his specification which does not contain any drawings. That is, notwithstanding the language of the Abstract (Lines 19-21 thereof) that the micro-pitted surfaces of Branemark may include elements that "may be shaped with grooves, corrugations, channels, etc, and be provided with an opening for tissue to grow through" still does not provide any specific suggestion of order, directionality or the like, much less a repetitive surface pattern as is taught by Appellants.

More importantly, while not teaching any type of repetitive surface pattern, given that 1000 nanometers equal 1 micron, the uppermost range of the magnitude of the micro-pits (or other structure) suggested by Branemark is but one-half of the low end (two microns) of the Appellants range (2-25 microns) of repetitive parallel alternating ridges and grooves. As such, most of the range of 10-1000 nanometers of Branemark constitutes a surface far too smooth to produce an orientation and directionality of growth of colonies of cells having sufficient contact with an implant surface. Further, Branemark notes (Col. 2, Line 41 thereof, that his preferred range is 10 to 30 nanometers (0.03 microns) thereby falling well below the low end of Appellants' range of dimensions. It is, thereby, to be appreciated that not only is the order of magnitudes of the "pits" of Branemark below that of Appellants' claimed range but, in addition, there is no teaching of the use of a repetitive surface pattern of any type, notwithstanding Branemark's comments that his elements may be shaped with grooves, corrugations, channels and the like. In fact, it is unclear from such language whether Branemark simply intends that his micro-pitted surface can be applied to an implant having grooves, corrugations and channels or, alternatively, whether or not such grooves,

corrugation and channels are the micro-pits. That is, Branemark apparently uses the term "element" to mean implant and that the implant may have both grooves and micro-pits.

With respect to the Examiner's assertion that "a micron is such a small unit of length, 1.0 micron (1000 nanometers)" it falls within the range of "about 2 microns," Appellants respectfully disagree. It is important to point out that regardless how small a unit is, the unit defines a definitive measurement range. Within that range, one "small" number can be significantly different from another "small" number. Therefore, it is only appropriate to judge whether two numbers overlap within the scope of a specifically defined unit, not how small that unit is.

More particularly, the Federal Circuit has held that the ordinary and accustomed meaning of "about" is "approximately." See Canopco., Inc. v. May Dept Store Co., 46 F.3d 1556, 1561 n.2 (Fed. Cir. 1994), quoting Webster's Third New International Dictionary. Further, Blacks Law Dictionary (7th Ed. 1999) defines "about" as approximately. In Modine Mfg. Co. v. U.S. International Trade Commission, 75 F. 3d 1545, 1554 (Fed. Cir. 1996), the Federal Circuit stated that the term "about" must be viewed by the decision maker as they would be understood by persons experienced in the field of the invention. Although it is rarely feasible to attach a precise limit to "about," the usage can usually be understood in light of the technology embodied in the invention."

Appellants particularly refer to Frilette v. Kimberlin, 412 F.2d. 1390, 1399 (CCPA 1969). In this interference case, prior art reciting a range of 3 to 5 Angstroms pore diameters of cyrstals was held not to read upon Applicant's range of pore diameters of about 6 to 15 Angstroms. [Emphasis added.] With the issue at hand, Branemark teaches micro-pits in a range of 10-1000 nanometers. This upper end of 1000 nanometers is substantially different from Appellants' lower end of about 2000 nanometers, therefore, it does not overlap with Appellants' claimed

range of dimension.

With further regard to the Abstract of Branemark, it is noted, at Line 9 thereof that "Optimal result are obtained with pore diameters equal to or smaller than 300 nanometers..." which is consistent with Branemark's recitation of the 10 to 300 nm range in Col. 2, Line 41 of his specification. Therein, it is also clear that Branemark equates a pore to a micro-pit. It is also clear that the pore size of Branemark is at its high end, one-half of the low end of the range of Appellants and, at its low end, .005 of the low end of Appellants' range. This fact taken in combination with the complete absence of any enabling teaching as to whether or not Branemark contemplated any form or repetitive surface pattern in that range, whether with or without grooves, corrugations, or channels, renders Branemark inoperative as a teaching or anticipatory reference.

With regard to the Examiner's argument related to the term "repetitive", Appellants urge that a dictionary definition of the term "repetitive" is not appropriate given that the Appellants have presented a lengthy specification, including many illustrations, to define their use of the term "repetitive" in the context of their invention (See for example Fig. 7 thru 14A of the Drawings and the description thereof at Pages 20-23 of the specification).

Therefore, Appellants maintain that Appellants' claimed invention is not anticipated or implied by Branemark et al.

(B) Claims 5-7, 9 and 12-19 have been rejected under 35 U.S.C. 102(e) as anticipated by Naiman, et al (U.S.P.N. 5,607,607). Appellants however have submitted a copy of the declaration of co-inventor John L. Ricci (see Declaration of November 23, 2001) in regard to Application Serial No. 09/500,038, which was furnished as an enclosure to Appellants' response of October 8, 2002. This declaration indicates that the present invention was conceived and reduced to

practice prior to the effective date (November 1, 1993) of Naiman et al. See 5 and 6 of said Declaration. As such, Naiman '607 cannot stand as a reference with respect to Claims 5-7, 9 and 12-19.

(C) Claims 5-7, 9, 14-16 and 19 were rejected under 35 U.S.C. 103(a) as unpatentable over Lin (U.S.P.N. 4,778,769) in view of Mears (U.S.P.N. 4,553,272) in the final Office Action. Therein, the Examiner appears to rely upon Mears' teaching of the use of "open pores of an average size of about 25 to 75 microns and a second series of open pores of average size of about 100 to 400 microns..." (See last sentence of Abstract of Mears). However, Appellants, as above noted, do not employ pores but, rather, employ a specific repetitive surface pattern in the form of multiplicity of substantially parallel ridges and grooves, each having an established width in a range of about 2 to about 25 microns and an established depth within a like range of dimensions. Accordingly, neither the geometry nor the dimensionality of Mears is congruent with that of the Appellants. Further, the teaching of Mears does not relate to an orthopedic implant but, rather, to one which addresses issues of soft tissue, namely, cartilages, tendons, ligaments, and musculo-tendenous cells which, while relative to certain areas of joint reconstruction, do not relate an implant for the surgical insertion into a bone or bone-related tissue of a patient.

From the illustration of Fig. 1 of Mears, it is clear that the use thereof is contemplated to re-establish a ball-and-socket hip joint of a patient. This may be fairly compared to Fig. 20 of Appellants' specification in which, as may be noted, the Appellants' micro-geometric repetitive surface pattern is applied to the stem 106 and shoulder 110 of a hip implant but not to ball portion 130 thereof which is the area to which Mears would have application.

Further, from the enlarged radial cross-sectional view of Fig. 2 of Mears, the lack of order to the pores 12 of Mears is also apparent, as is that of pores 44

and 46 of Figs. 3 and 5 in which Mears shows a dental application of his soft tissue implant. It is further noted that the only actual teaching of Mears is that his pores occupy between about 20 and about 50 percent of the total volume of the portion of the implant upon which they are used. (See Col. 3, Line 59 to 63). Accordingly, there is no order or pattern in the use of the open pore geometry of Mears other than that their total volume occupy 20 to 50 percent of the volume of the implant surface to which they are applied.

With regard to the reference to Lin, which the Examiner has applied as a teaching reference in combination with Mears, it is respectfully noted that Lin relates to a dissolvable spacer used in a calcium sulfate acid etch process upon a plastic surface. Thereby, the acid etch mask and process of Lin is not applicable to high density materials such as titanium, stainless steel, ceramics, Hench glass and combinations thereof employed as a base material in Appellants' implant. The present application makes reference to such high density base material of the implant in Claims 5 and 18 of the application. As noted by Appellants at Page 7, the first paragraph, of the specification, Lin employs an acid soluble spacer which contains a pattern to be transferred to the implant surface which, as such, is positioned upon a desired portion of the implant surface to be texturized. The spacer is then pressed into the implant surface and is then removed by treating it with an acid. This process, as above noted, is not applicable to the high density materials which must be employed in any orthopedic application of Appellants' invention.

In addition to the above, Lin and Mears, however combined, do not teach an essential limitation of Appellants invention, namely, a repetitive surface pattern in the form of multiplicity of substantially parallel alternating ridges and grooves. That is, as may be seen in Figs. 1-3 of Lin, the geometry thereof is not one of substantially parallel ridges and grooves but, rather, is one more akin to a honeycomb pattern. This pattern is described by Lin at Col. 2, Lines 53-56 to the

effect that "pattern 14 includes tapered post 16 with undercuts 18 as well as pyramids 17 and triangular ridges 19, as shown in Figs. 3 and 5." The process by which this rather complex geometry is formed is further described by Lin at Col. 3, Lines 17-19 thereof. As such, Mears does not teach the use of substantially parallel pattern of alternating ridges and grooves. And certainly, does not suggest any dimensionality whatsoever. Thereby, Lin and Mears, however combined, do not teach a high density implant element having the limitations of dimension and geometry claimed by Appellants. In fact, these limitations are critical in the accomplishment of the objects of the invention, as is set forth in Appellants' Declaration under 37 C.F.R. 1.132 (combined with said 1.131 Declaration) furnished as Enclosure 4 with Appellants' Amendment/Response of October 8, 2002. Therein, the remarks made relative to Wagner (U.S.P.N. 5,989,027) in ¶10-13 of said Declaration which relate to an essentially random, irregular porous surface, are equally applicable to the random open pore structure of Mears. Therefore, the references to Lin and Mears, however combined, do not render obvious Appellants' Claims 5-7, 9, 14-16 and 19.

Furthermore, as discussed previously, with regard to the Examiner's argument related to the term "repetitive", Appellants urge that a dictionary definition of the term "repetitive" is not appropriate given that the Appellants have presented a lengthy specification, including many illustrations, to define their use of the term "repetitive" in the context of their invention (See for example Fig. 7 thru 14A of the Drawings and the description thereof at Pages 20-23 of the specification).

Therefore, Appellants maintain that Appellants' claimed invention is not obvious in view of the prior art.

9. CONCLUSION

Accordingly, for all the reasons expressed above, the final rejection of the Claims on Appeal should be reversed by the Board and the extant claims of the application should be allowed to issue.

10-14-03
Date of Signature

By: _____
Melvin K. Silverman
Reg. No. 26,234
Attorney for Appellant

Address correspondence to:

Melvin K. Silverman
500 Cypress Creek Road
Suite 500
Fort Lauderdale, Florida 33309
Telephone: (954) 351-7474
Facsimile: (954) 492-0087

APPENDIX A – CLAIMS ON APPEAL

5. (Previously presented). The implant as recited in Claim 14 in which base materials of said implant are selected from the group consisting of the materials of titanium and alloys thereof, stainless steel, ceramics, biocompatible glass and combinations thereof.

7. (Previously presented). The implant as recited in Claim 14 in which said repetitive micro-geometric pattern of ridges and grooves comprises application to surfaces of said implant element in orientations which, relative to a longitudinal axis of said implant, are selected from the group consisting of vertical, horizontal, orthonormal diagonal, radial, circumferential, and concentric orientations.

9. (Previously presented). The implant as recited in Claim 14 in which said orthopedic implant is selected from the group consisting of hip, knee, shoulder, elbow, ankle and finger implants.

12. (Original). The implant as recited in claim 9 comprising different zones furnished with respectively different surface patterns.

13. (Original). The implant as recited in Claim 12 in which said different zones include respective hard and soft tissue contact zones

14. (Previously presented). An orthopedic implant comprising an implant element for surgical insertion into a bone or bone-related tissue of a patient, said implant element comprising a micro-geometric, repetitive surface pattern in a form of a multiplicity of substantially parallel alternating ridges and grooves, each having an established width in a range of about 2 to about 25 microns, and an established depth in a range of about 2 to about 25 microns,

whereby said micro-geometric repetitive pattern defines a guide for a promotion of the rate, orientation and direction of growth of colonies of cells of said bone which are in contact with said surface pattern.

15. (Previously presented). The implant as recited in Claim 14, in which said implant element comprises a grid-like matrix of said pattern of alternating ridges and grooves.

16. (Previously presented). The implant as recited in Claim 14, in which said alternating ridges and grooves are oriented in parallel with a longitudinal axis of said implant.

17. (Previously presented). The implant as recited in Claim 14, in which said alternating ridges and grooves are oriented transversely to said longitudinal axis of said implant.

18. (Previously presented). The implant as recited in Claim 5, in which the surface of said implant element comprises a surface selected from the group of surfaces consisting of hydroxyapatite, RBM roughening, titanium, plasma sprayed, calcium sulfate, biocompatible glass, collagen, growth factor compounds, and combination thereof.

19. (Previously presented). The implant as recited in claim 9, in which said repetitive micro-geometric pattern is [comprises] a product of the process group consisting of laser etching, acid etching, mechanical etching, and photolithography.